K091472 1/1

Section 5 – 510(k) Summary

JUN 12 2009

Applicant:	Anulex Technologies, Inc. 5600 Rowland Road, Suite 280 Minnetonka, MN 55343
Contact Person:	Rachel Kennedy Senior Regulatory Affairs Manager Telephone: 952.224.4034 Fax: 952.224.4040 e-mail: rkennedy@anulex.com
Date Prepared:	May 13, 2009
Trade Name:	Xclose™ Tissue Repair System
Product Classification and Code:	21 CFR §878.5000 Class: II Product Code: GAT
Predicate Device:	K062307 – Xclose Tissue Repair System
Device Description:	The modified Xclose™ Tissue Repair System consists of two (2) non-absorbable braided surgical 3-0 suture (Ultra High Molecular Weight Polyethylene, UHMWPE) and T-anchor (polyethylene terephthalate, PET) assemblies, connected together with a loop of green 2-0 suture (PET). The 2-0 suture loop is used to facilitate tightening, drawing the 3-0 suture/anchor assemblies together, thereby re-approximating the tissue. The suture components conform to USP requirements The construct is provided sterile and preloaded on a disposable delivery instrument.
Intended Use:	The Xclose™ Tissue Repair System is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.
Summary of Technological Characteristics:	The modifications to the Xclose Tissue Repair System were conducted in accordance with the Anulex Design Control System. Accordingly, the risk analysis identified necessary design verification and validation activities. As a result of this analysis, tensile testing was performed to confirm compliance to USP suture requirements.
Conclusion:	The modified Xclose™ Tissue Repair System is substantially equivalent to the original Xclose Tissue Repair System in regards to the indications for use, technology and the basic operating principle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

Anulex Technologies, Incorporated
% Ms. Rachel Kennedy
Senior Regulatory Affairs Manager
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 55343

Re: K091432
Trade/Device Name: Xclose™ Tissue Repair System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(ethylene terephthalate) Surgical Suture
Regulatory Class: II
Product Code: GAT
Dated: May 13, 2009
Received: May 14, 2009

Dear Ms. Kennedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091432 1/1

Section 4 – Indications For Use Statement

510(k) Number (if known): K_____

Device Name: Xclose™ Tissue Repair System

Indications for Use:

The Xclose™ Tissue Repair System is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091432